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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,234	06/04/2001	Ernesto Palazzini	9457-023	4468

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NEW YORK, NY 100362711

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,234

Applicant(s)

PALAZZINI ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,27 and 29-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,27 and 29-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Objections/Rejections Set For the in Office Action dated May 7, 2002

1. Claims 1 and 8-24 are objected to because of the following informalities: A space should be added to "100mg" and "1000mg" after last numeral of the number in the third line of claim 1.
2. Claims 28-29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim.
3. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites the limitation "method of claim 15" in the first line of claim 27. There is insufficient antecedent basis for this limitation in the claim.
4. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cristofori et al. US 5,252,339 (Cristofori).
5. Claims 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchi et al. US 5,496,807 (Marchi).
6. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cristofori et al. US 5,252,339 (Cristofori), Marchi et al. US 5,496,807 (Marchi), and Baggio et al. US 5,686,432 (Baggio).

Applicant's Response dated September 24, 2002

7. In the amendment filed September 24, 2002 claims 30-36 have been added, claims 26, 27, and 29 were amended, and claim 1-25 and 28 were canceled. An action on the merits of claims 26-27 and 29-36 is contained herein below.

8. In regards to objections to claims 1, 8-24, and 28-29, applicant's amendments dated September 24, 2002 have been fully considered and have overcome the objections set forth in the Office Action dated May 7, 2002 or have been rendered moot in view of the cancellation of claims.

9. In regard to the rejection of claim 27 under 35 U.S.C § 112, second paragraph, applicant's amendments have been considered and have overcome the rejection set forth in the Office Action dated May 7, 2002.

10. In regard to the rejection of claims 1-10 under 35 U.S.C § 102(b), applicant's amendments have rendered the rejection set forth in the Office Action dated May 7, 2002 moot in view of the cancellation of claims.

11. In regard to the rejection of claims 26-27 under 35 U.S.C § 102(b), applicant's amendments have been fully considered and have overcome the rejection set forth in the Office Action dated May 7, 2002.

12. In regard to the rejection of claims 1-25 under 35 U.S.C § 103(a), applicant's amendments have rendered the rejection set forth in the Office Action dated May 7, 2002 moot in view of the cancellation of claims.

13. The rejection of claims 26-27 under 35 U.S.C. 103(a) has been maintained for the reasons of record set forth in the Office Action dated June 27, 2002. The cited art of

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record is also seen to render amended claim 29 and newly added claims 30-36 obvious and will be addressed in a separate rejection herein below.

Response to Arguments

14. In regard to the rejection of claims 26-27 (and as it relates to amended claim 29 and newly added claims 30-36) under 35 U.S.C § 103(a), applicant's arguments have been considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The examiner further disagrees with applicant's characterization of the cited art of record. Cristofori teaches pharmaceutical compositions for oral use comprising sulodexide (column 3, lines 34-43). The composition may be in the form of tablets or capsules (hard or soft) (column 4, lines 12-34). Baggio teaches sulodexide as preventing and curing the nephropathy caused by diabetes by fighting against the phenomena that cause the alterations of the renal structure and function (column 1, lines 59-65). Baggio further teaches dosages of up to 500 mg of sulodexide for the treatment of renal insufficiency [diabetic nephropathy caused by renal insufficiency] (column 2, lines 36-44). Marchi also teaches the treatment of diabetic nephropathy by administering sulodexide (Abstract). It indeed would have been obvious to one of

ordinary skill in the art at the time of the invention to combine the teachings of Cristofori, Baggio, and Marchi to arrive at the instant invention as Baggio teaches dosages of up to 500 mg of sulodexide for the treatment of renal insufficiency [diabetic nephropathy caused by renal insufficiency].

In response to applicant's argument of unexpected results, burden is on applicant to establish that results are unexpected and significant in a declaration or affidavit. Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art, which is commensurate in scope with the claims. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range.

Claim Rejections - 35 USC § 103

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Baggio et al. US 5,686,432 (Baggio), Cristofori et al. US 5,252,339 (Cristofori), and Marchi et al. US 5,496,807 (Marchi).

Claims 29-36 are drawn to a method of treating diabetic nephropathy comprising administering at least 200 mg/day of sulodexide or a pharmaceutically acceptable salt.

Baggio teaches sulodexide as preventing and curing the nephropathy caused by diabetes by fighting against the phenomena that cause the alterations of the renal

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structure and function (column 1, lines 59-65). Baggio further teaches dosages of up to 500 mg of sulodexide for the treatment of renal insufficiency [diabetic nephropathy caused by renal insufficiency] (column 2, lines 36-44).

Baggio differs from the instantly claimed invention in that Baggio: 1) does not teach oral administration of the sulodexide composition; and 2) does not teach administration of greater than 500 mg of sulodexide. Although Baggio does not teach administration of 525 mg of sulodexide, the difference between the administrations of 500 mg compared to 525 mg of sulodexide is not seen to add patentability over the prior art. A *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Cristofori and Marchi teach oral administration of sulodexide.

Cristofori discloses pharmaceutical compositions for oral use comprising sulodexide (column 3, lines 34-43). The composition may be in the form of tablets or capsules (hard or soft) (column 4, lines 12-34).

Marchi discloses pharmaceutical compositions of sulodexide for the treatment of diabetic nephropathy. The composition may be in the form of tablets, capsules, granulates, or syrups for oral administration (column 3, lines 1-5).

It indeed would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Cristofori, Baggio, and Marchi to arrive at the instant invention as Baggio teaches dosages of up to 500 mg of sulodexide, which is taught in the prior art as being suitable for oral administration, for the treatment of renal

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insufficiency [diabetic nephropathy caused by renal insufficiency]. One would have been motivated to do so in order to provide effective treatment since factors such as the extent of the illness and body weight of the patient could render conventional compositions ineffective. Thus, the instant invention is seen to be within the purview of the skilled artisan.

Conclusion

17. Claims 26-27 and 29-36 are pending. Claims 26-27 and 29-36 are rejected. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

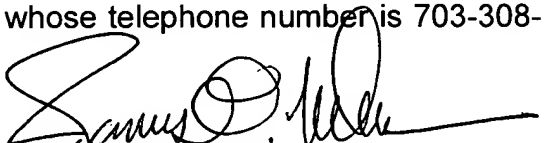
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
December 13, 2002